

**PFIZER-BIONTECH COVID-19 VACCINE- bnt162b2 injection, suspension**  
**Pfizer Manufacturing Belgium NV**

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**PFIZER-BIONTECH COVID-19 VACCINE**

**FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE**  
**(VACCINATION PROVIDERS)**

**EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19**  
**VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

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| <p><b>FOR 12 YEARS OF AGE AND OLDER</b><br/><b>DO NOT DILUTE</b></p> |
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The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 5 years of age and older.

There are 2 formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older:

The formulation supplied in a multiple dose vial with a gray cap and label with a gray border **IS NOT DILUTED PRIOR TO USE.**

The formulation supplied in a multiple dose vial with a purple cap **MUST BE DILUTED PRIOR TO USE.**

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border which is authorized for use in individuals 12 years of age and older and **MUST NOT BE DILUTED PRIOR TO USE.**

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border is authorized for use to provide:

- a 2-dose primary series to individuals 12 years of age and older;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise;
- a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in

**individuals 16 years of age and older. It is also authorized for emergency use to provide:**

- **a 2-dose primary series to individuals 12 through 15 years of age;**
- **a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise;**
- **a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and**
- **a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.**

**The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use can be used interchangeably.<sup>1</sup>**

**COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.<sup>2</sup>**

## **SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS**

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection.

### Primary Series:

The Pfizer-BioNTech COVID-19 Vaccine is administered as a primary series of 2 doses (0.3 mL each) 3 weeks apart in individuals 12 years of age or older.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

### Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals 18 years of age and older.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another

authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

## DOSAGE AND ADMINISTRATION

The storage, preparation, and administration information in this Fact Sheet apply to the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, which is supplied in a multiple dose vial with a gray cap and a label with a gray border and **MUST NOT** be diluted prior to use.

### Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Gray Cap and a Label with a Gray Border

| Age Range          | Dilution Information       | Doses Per Vial | Dose Volume |
|--------------------|----------------------------|----------------|-------------|
| 12 years and older | Do not dilute prior to use | 6              | 0.3 mL      |

## Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

### Vial Storage Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F).

Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 6 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -

60°C (-130°F to -76°F). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.

### Vial Storage During Use

If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after first puncture.

### **DO NOT DILUTE PRIOR TO USE.**

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Fact Sheet supersedes the number of hours printed on vial labels and cartons.

### Transportation of Vials

If local redistribution is needed, vials may be transported at -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F).

### **Dosing and Schedule**

#### Primary Series

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 2 doses (0.3 mL each) 3 weeks apart to individuals 12 years of age and older.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

#### Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals 18 years of age and older.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized

formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

### Dose Preparation

#### **DO NOT DILUTE**

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with a gray cap and a label with a gray border contains a volume of 2.25 mL, and is supplied as a frozen suspension that does not contain preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)].
- Refer to thawing instructions in the panels below.
- One vial contains 6 doses of 0.3 mL.

#### **Preparation Instructions**

##### **Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border - Vial Verification**



✓ **Gray plastic cap and label with gray border.**

Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a gray plastic cap and a label with gray border.

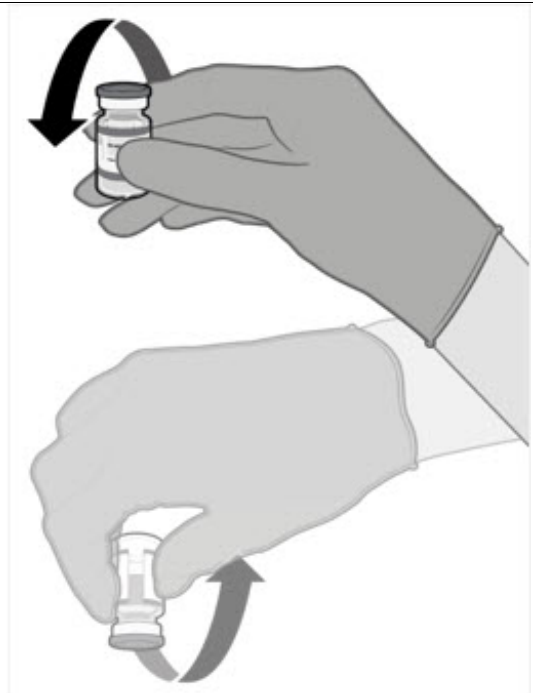
##### **Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border - Thawing Prior to Use**

- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials



Each vial may take up to 6 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.

- Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.

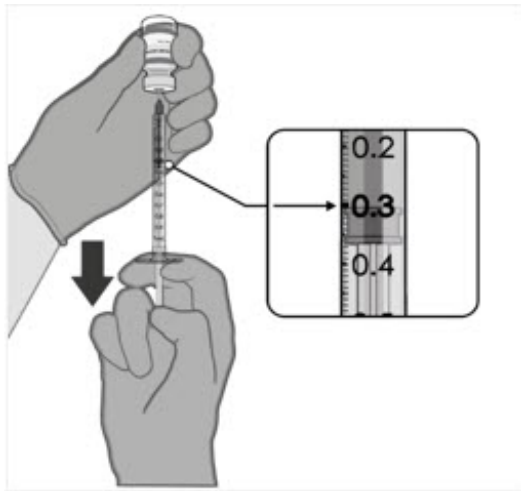


**Gently × 10**

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discolored or if particles are observed after mixing.

**Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border - Preparation of Individual 0.3 mL Doses**

- Using aseptic technique, cleanse the vial stopper



**Withdraw 0.3 mL dose of vaccine.**

with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, preferentially using a low dead-volume syringe and/or needle.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately.



**Record the date and time of first puncture.  
Use within 12 hours after first puncture.**

- Record the date and time of first vial puncture on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture.

## Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Vials of Pfizer-BioNTech COVID-19 Vaccine with gray caps and labels with gray borders contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be

used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

## **Contraindications**

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (*see Full EUA Prescribing Information*).

## **Warnings**

### Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

### Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

### Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

### Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

### Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## **Adverse Reactions**



### *Adverse Reactions in Clinical Trials*

Adverse reactions following administration of the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, lymphadenopathy, decreased appetite, rash, and pain in extremity (see *Full EUA Prescribing Information*).

### *Adverse Reactions in Post Authorization Experience*

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

### **Use with Other Vaccines**

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

### **INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS**

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website [www.cvdvaccine.com](http://www.cvdvaccine.com) to obtain the Vaccine Information Fact Sheet) prior to the individual receiving each dose of the Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information,

visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

## **MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION<sup>3</sup>**

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 5 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events\* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
  - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at

<https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

\* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent 1 of the outcomes listed above.

## **OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.**

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.


To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

| <b>Website</b>   | <b>Fax number</b> | <b>Telephone number</b> |
|--|-------------------|-------------------------|
| <a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a> | 1-866-635-8337    | 1-800-438-1985          |

## **ADDITIONAL INFORMATION**

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

| <b>Global website</b>   | <b>Telephone number</b>            |
|---|------------------------------------|
| <a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a><br> | 1-877-829-2619<br>(1-877-VAX-CO19) |

## **AVAILABLE ALTERNATIVES**

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for administration errors, including dosing errors.

## **FEDERAL COVID-19 VACCINATION PROGRAM**

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html>.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

## **AUTHORITY FOR ISSUANCE OF THE EUA**

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the

COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, and for certain uses of FDA-approved COMIRNATY for active immunization against COVID-19.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

### **The Countermeasures Injury Compensation Program**

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp), email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call: 1-855-266-2427.



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55131 Mainz, Germany

LAB-1484-2.0

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END SHORT VERSION FACT SHEET

Long Version (Full EUA Prescribing Information) Begins On Next Page

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1 When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

- 2 Notwithstanding the age limitations for use of the different formulations and presentations described above, individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA) (orange cap); or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 mcg modRNA) (gray and purple cap).
- 3 Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

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**FULL EMERGENCY USE  
AUTHORIZATION (EUA) PRESCRIBING  
INFORMATION  
PFIZER-BIONTECH COVID-19 VACCINE**

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\* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

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**FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION****1 AUTHORIZED USE**

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

This EUA Prescribing Information pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and label with a gray border, which is authorized for use in individuals 12 years of age and older.

**2 DOSAGE AND ADMINISTRATION**

For intramuscular injection only.

The storage, preparation, and administration information in this Prescribing Information apply to the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, which is supplied in a multiple dose vial with a gray cap and label with a gray border and **MUST NOT** be diluted prior to use.

**Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial  
with Gray Cap and a Label with a Gray Border**

| <b>Age Range</b>   | <b>Dilution Information</b> | <b>Doses Per Vial</b> | <b>Dose Volume</b> |
|--------------------|-----------------------------|-----------------------|--------------------|
| 12 years and older | Do not dilute prior to use  | 6                     | 0.3 mL             |

**2.1 Preparation for Administration****DO NOT DILUTE**

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with a gray cap and a label with a gray border contains a volume of 2.25 mL, and is supplied as a frozen suspension that does not contain preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] [*see How Supplied/Storage and Handling (19)*].
- Refer to thawing instructions in the panels below.
- One vial contains 6 doses of 0.3 mL.

## Preparation Instructions

### Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border - Vial Verification



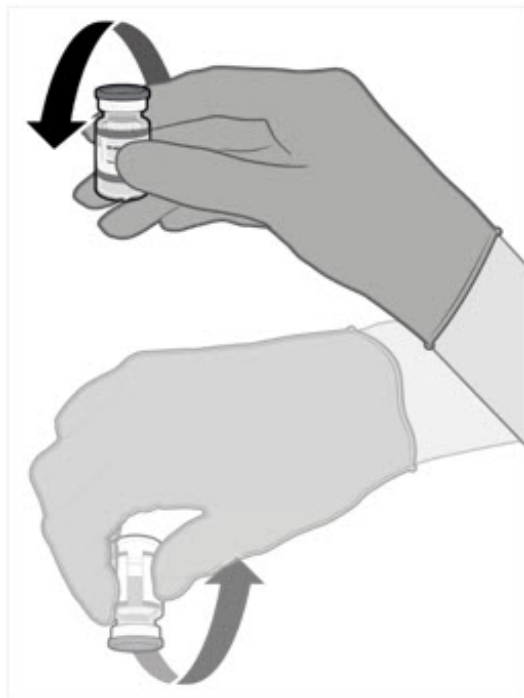
✓ **Gray plastic cap and label with gray border.**

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a gray plastic cap and a label with a gray border.

### Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border - Thawing Prior to Use



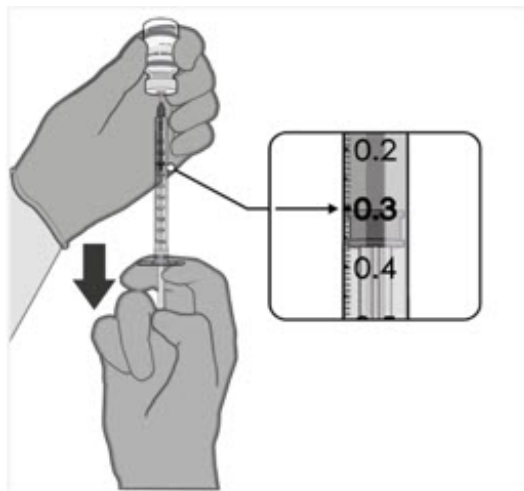
- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine (Do Not Dilute, for 12 years of age and older) before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 6 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



**Gently × 10**

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discolored or if particles are observed after mixing.

**Pfizer-BioNTech COVID-19 Vaccine Vial with Gray Cap and Label with Gray Border -  
Preparation of Individual 0.3 mL Doses**



**Withdraw 0.3 mL dose of vaccine.**

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately.





**Record the date and time of first puncture.  
Use within 12 hours after first puncture.**

- Record the date and time of first vial puncture on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture.

## 2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Vials of Pfizer-BioNTech COVID-19 Vaccine with gray caps and labels with gray borders contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

## 2.3 Vaccination Schedule

### Primary Series

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 2 doses (0.3 mL each) 3 weeks apart in individuals 12 years of age and older.

A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed

with conditions that are considered to have an equivalent level of immunocompromise.

### **Booster Dose**

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals 18 years of age and older.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

## **3 DOSAGE FORMS AND STRENGTHS**

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in vials with gray caps and labels with gray borders is 0.3 mL for individuals 12 years of age and older [*see Dosage and Administration (2.1)*].

## **4 CONTRAINDICATIONS**

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine [*see Description (13)*].

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Management of Acute Allergic Reactions**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

### **5.2 Myocarditis and Pericarditis**

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

### 5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

### 5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

### 5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## 6 OVERALL SAFETY SUMMARY

**It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine.<sup>4</sup> To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.**

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<sup>4</sup> Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

### Primary Series

In clinical studies of participants 16 years of age and older who received Pfizer-BioNTech COVID-19 Vaccine containing 30 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 (30 mcg modRNA), adverse reactions following administration of the primary series included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

In a clinical study in adolescents 12 through 15 years of age who received Pfizer-

BioNTech COVID-19 Vaccine (30 mcg modRNA), adverse reactions following administration of the primary series included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

### Booster Dose

In a clinical study of participants 18 through 55 years of age, adverse reactions following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

### Post Authorization Experience

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

## **6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

### Primary Series

The safety of the primary series Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 12 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.

Study BNT162-01 (Study 1) was a Phase 1/2, 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants [21,720 Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2; 21,728 placebo] in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

In Study 2, all participants 12 through 15 years of age, and 16 years of age and older in the reactogenicity subset, were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 6 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo.

### Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 [18,801 Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) and 18,785 placebo] participants 16 years of age or older had been followed for a median of 2 months after the second dose.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years of age and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

### *Solicited Local and Systemic Adverse Reactions*

Across both age groups, 18 through 55 years of age and 56 years of age and older, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

**Table 1: Study 2 - Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose - Participants 18 Through 55 Years of Age\* - Reactogenicity Subset of the Safety Population†**

|   | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>‡</sup><br/>Dose 1<br/>N<sup>§</sup>=2291<br/>n<sup>¶</sup> (%)</b> | <b>Placebo<br/>Dose 1<br/>N<sup>§</sup>=2298<br/>n<sup>¶</sup> (%)</b> | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>‡</sup><br/>Dose 2<br/>N<sup>§</sup>=2098<br/>n<sup>¶</sup> (%)</b> | <b>Placebo<br/>Dose 2<br/>N<sup>§</sup>=2103<br/>n<sup>¶</sup> (%)</b> |
|---|---|--|---|--|
| <b>Redness<sup>#</sup></b>                    |   |  |   |  |
| Any (>2 cm)                                   | 104 (4.5)   | 26 (1.1)   | 123 (5.9)   | 14 (0.7)   |
| Mild  | 70 (3.1)  | 16 (0.7)   | 73 (3.5)  | 8 (0.4)  |
| Moderate                                      | 28 (1.2)  | 6 (0.3)  | 40 (1.9)  | 6 (0.3)  |
| Severe  | 6 (0.3)   | 4 (0.2)  | 10 (0.5)  | 0 (0.0)  |
| <b>Swelling<sup>#</sup></b>                   |   |  |   |  |
| Any (>2 cm)                                   | 132 (5.8)   | 11 (0.5)   | 132 (6.3)   | 5 (0.2)  |
| Mild  | 88 (3.8)  | 3 (0.1)  | 80 (3.8)  | 3 (0.1)  |
| Moderate                                      | 39 (1.7)  | 5 (0.2)  | 45 (2.1)  | 2 (0.1)  |
| Severe  | 5 (0.2)   | 3 (0.1)  | 7 (0.3)   | 0 (0.0)  |
| <b>Pain at the injection site<sup>p</sup></b> |   |  |   |  |
| Any   | 1904 (83.1)   | 322 (14.0)   | 1632 (77.8)   | 245 (11.7)   |
| Mild  | 1170 (51.1)   | 308 (13.4)   | 1039 (49.5)   | 225 (10.7)   |

|          |            |          |            |          |
|----------|------------|----------|------------|----------|
| Moderate | 710 (31.0) | 12 (0.5) | 568 (27.1) | 20 (1.0) |
| Severe   | 24 (1.0)   | 2 (0.1)  | 25 (1.2)   | 0 (0.0)  |

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

\* Eight participants were between 16 and 17 years of age.

† Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

‡ Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

§ N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

¶ n = Number of participants with the specified reaction.

# Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

Ⓟ Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

**Table 2: Study 2 - Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose - Participants 18 Through 55 Years of Age\* - Reactogenicity Subset of the Safety Population†**

|                   | <b>Pfizer-BioNTech COVID-19 Vaccine‡<br/>Dose 1<br/>N§=2291<br/>n¶ (%)</b> | <b>Placebo<br/>Dose 1<br/>N§=2298<br/>n¶ (%)</b> | <b>Pfizer-BioNTech COVID-19 Vaccine‡<br/>Dose 2<br/>N§=2098<br/>n¶ (%)</b> | <b>Placebo<br/>Dose 2<br/>N§=2103<br/>n¶ (%)</b> |
|-------------------|--|--|--|--|
| <b>Fever</b>      |  |  |  |  |
| ≥38.0°C           | 85 (3.7)   | 20 (0.9)   | 331 (15.8)   | 10 (0.5)   |
| ≥38.0°C to 38.4°C | 64 (2.8)   | 10 (0.4)   | 194 (9.2)  | 5 (0.2)  |
| >38.4°C to 38.9°C | 15 (0.7)   | 5 (0.2)  | 110 (5.2)  | 3 (0.1)  |
| >38.9°C to 40.0°C | 6 (0.3)  | 3 (0.1)  | 26 (1.2)   | 2 (0.1)  |
| >40.0°C           | 0 (0.0)  | 2 (0.1)  | 1 (0.0)  | 0 (0.0)  |
| <b>Fatigue#</b>   |  |  |  |  |
| Any               | 1085 (47.4)  | 767 (33.4)                                       | 1247 (59.4)  | 479 (22.8)                                       |
| Mild              | 597 (26.1)   | 467 (20.3)                                       | 442 (21.1)   | 248 (11.8)                                       |
| Moderate          | 455 (19.9)   | 289 (12.6)                                       | 708 (33.7)   | 217 (10.3)                                       |
| Severe            | 33 (1.4)   | 11 (0.5)   | 97 (4.6)   | 14 (0.7)   |
| <b>Headache#</b>  |  |  |  |  |
| Any               | 959 (41.9)   | 775 (33.7)                                       | 1085 (51.7)  | 506 (24.1)                                       |
| Mild              | 628 (27.4)   | 505 (22.0)                                       | 538 (25.6)   | 321 (15.3)                                       |
| Moderate          | 308 (13.4)   | 251 (10.9)                                       | 480 (22.9)   | 170 (8.1)  |
| Severe            | 23 (1.0)   | 19 (0.8)   | 67 (3.2)   | 15 (0.7)   |
| <b>Chills#</b>    |  |  |  |  |
| Any               | 321 (14.0)   | 146 (6.4)  | 737 (35.1)   | 79 (3.8)   |
| Mild              | 230 (10.0)   | 111 (4.8)  | 359 (17.1)   | 65 (3.1)   |
| Moderate          | 82 (3.6)   | 33 (1.4)   | 333 (15.9)   | 14 (0.7)   |

|  |            |            |            |            |
|--|------------|------------|------------|------------|
| Severe   | 9 (0.4)    | 2 (0.1)    | 45 (2.1)   | 0 (0.0)    |
| Vomiting <sup>p</sup>                              |            |            |            |            |
| Any  | 28 (1.2)   | 28 (1.2)   | 40 (1.9)   | 25 (1.2)   |
| Mild   | 24 (1.0)   | 22 (1.0)   | 28 (1.3)   | 16 (0.8)   |
| Moderate   | 4 (0.2)    | 5 (0.2)    | 8 (0.4)    | 9 (0.4)    |
| Severe   | 0 (0.0)    | 1 (0.0)    | 4 (0.2)    | 0 (0.0)    |
| Diarrhea <sup>ß</sup>                              |            |            |            |            |
| Any  | 255 (11.1) | 270 (11.7) | 219 (10.4) | 177 (8.4)  |
| Mild   | 206 (9.0)  | 217 (9.4)  | 179 (8.5)  | 144 (6.8)  |
| Moderate   | 46 (2.0)   | 52 (2.3)   | 36 (1.7)   | 32 (1.5)   |
| Severe   | 3 (0.1)    | 1 (0.0)    | 4 (0.2)    | 1 (0.0)    |
| New or worsened muscle pain <sup>#</sup>           |            |            |            |            |
| Any  | 487 (21.3) | 249 (10.8) | 783 (37.3) | 173 (8.2)  |
| Mild   | 256 (11.2) | 175 (7.6)  | 326 (15.5) | 111 (5.3)  |
| Moderate   | 218 (9.5)  | 72 (3.1)   | 410 (19.5) | 59 (2.8)   |
| Severe   | 13 (0.6)   | 2 (0.1)    | 47 (2.2)   | 3 (0.1)    |
| New or worsened joint pain <sup>#</sup>            |            |            |            |            |
| Any  | 251 (11.0) | 138 (6.0)  | 459 (21.9) | 109 (5.2)  |
| Mild   | 147 (6.4)  | 95 (4.1)   | 205 (9.8)  | 54 (2.6)   |
| Moderate   | 99 (4.3)   | 43 (1.9)   | 234 (11.2) | 51 (2.4)   |
| Severe   | 5 (0.2)    | 0 (0.0)    | 20 (1.0)   | 4 (0.2)    |
| Use of antipyretic or pain medication <sup>à</sup> | 638 (27.8) | 332 (14.4) | 945 (45.0) | 266 (12.6) |

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

\* Eight participants were between 16 and 17 years of age.

† Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

‡ Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

§ N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

¶ n = Number of participants with the specified reaction.

# Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

p Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

ß Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

à Severity was not collected for use of antipyretic or pain medication.

**Table 3: Study 2 - Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose - Participants 56 Years of Age and Older - Reactogenicity Subset of the Safety Population\***

|  | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup></b> | <b>Placebo Dose 1<br/>N=1702</b> | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup></b> | <b>Placebo Dose 2<br/>N=1646</b> |
|--|---|----------------------------------|---|----------------------------------|
|--|---|----------------------------------|---|----------------------------------|

|                                    | <b>Dose 1</b><br><b>N†=1802</b><br><b>n§ (%)</b> | <b>N†=1792</b><br><b>n§ (%)</b> | <b>Dose 2</b><br><b>N†=1660</b><br><b>n§ (%)</b> | <b>N†=1646</b><br><b>n§ (%)</b> |
|------------------------------------|--|---------------------------------|--|---------------------------------|
| <b>Redness¶</b>                    |  |                                 |  |                                 |
| Any (>2 cm)                        | 85 (4.7)   | 19 (1.1)                        | 120 (7.2)  | 12 (0.7)                        |
| Mild                               | 55 (3.1)   | 12 (0.7)                        | 59 (3.6)   | 8 (0.5)                         |
| Moderate                           | 27 (1.5)   | 5 (0.3)                         | 53 (3.2)   | 3 (0.2)                         |
| Severe                             | 3 (0.2)  | 2 (0.1)                         | 8 (0.5)  | 1 (0.1)                         |
| <b>Swelling¶</b>                   |  |                                 |  |                                 |
| Any (>2 cm)                        | 118 (6.5)  | 21 (1.2)                        | 124 (7.5)  | 11 (0.7)                        |
| Mild                               | 71 (3.9)   | 10 (0.6)                        | 68 (4.1)   | 5 (0.3)                         |
| Moderate                           | 45 (2.5)   | 11 (0.6)                        | 53 (3.2)   | 5 (0.3)                         |
| Severe                             | 2 (0.1)  | 0 (0.0)                         | 3 (0.2)  | 1 (0.1)                         |
| <b>Pain at the injection site#</b> |  |                                 |  |                                 |
| Any (>2 cm)                        | 1282 (71.1)                                      | 166 (9.3)                       | 1098 (66.1)                                      | 127 (7.7)                       |
| Mild                               | 1008 (55.9)                                      | 160 (8.9)                       | 792 (47.7)                                       | 125 (7.6)                       |
| Moderate                           | 270 (15.0)                                       | 6 (0.3)                         | 298 (18.0)                                       | 2 (0.1)                         |
| Severe                             | 4 (0.2)  | 0 (0.0)                         | 8 (0.5)  | 0 (0.0)                         |

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

# Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

**Table 4: Study 2 - Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose - Participants 56 Years of Age and Older - Reactogenicity Subset of the Safety Population\***

|                   | <b>Pfizer-BioNTech COVID-19 Vaccine†</b><br><b>Dose 1</b><br><b>N†=1802</b><br><b>n§ (%)</b> | <b>Placebo</b><br><b>Dose 1</b><br><b>N†=1792</b><br><b>n§ (%)</b> | <b>Pfizer-BioNTech COVID-19 Vaccine†</b><br><b>Dose 2</b><br><b>N†=1660</b><br><b>n§ (%)</b> | <b>Placebo</b><br><b>Dose 2</b><br><b>N†=1646</b><br><b>n§ (%)</b> |
|-------------------|--|--|--|--|
| <b>Fever</b>      |  |  |  |  |
| ≥38.0°C           | 26 (1.4)   | 7 (0.4)  | 181 (10.9)   | 4 (0.2)  |
| ≥38.0°C to 38.4°C | 23 (1.3)   | 2 (0.1)  | 131 (7.9)  | 2 (0.1)  |
| >38.4°C to 38.9°C | 1 (0.1)  | 3 (0.2)  | 45 (2.7)   | 1 (0.1)  |
| >38.9°C to        | 1 (0.1)  | 2 (0.1)  | 5 (0.3)  | 1 (0.1)  |



|  |            |            |            |            |
|--|------------|------------|------------|------------|
| 40.0°C                                   | 1 (0.1)    | 2 (0.1)    | 3 (0.3)    | 1 (0.1)    |
| >40.0°C                                  | 1 (0.1)    | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    |
| Fatigue <sup>¶</sup>                     |            |            |            |            |
| Any                                      | 615 (34.1) | 405 (22.6) | 839 (50.5) | 277 (16.8) |
| Mild                                     | 373 (20.7) | 252 (14.1) | 351 (21.1) | 161 (9.8)  |
| Moderate                                 | 240 (13.3) | 150 (8.4)  | 442 (26.6) | 114 (6.9)  |
| Severe                                   | 2 (0.1)    | 3 (0.2)    | 46 (2.8)   | 2 (0.1)    |
| Headache <sup>¶</sup>                    |            |            |            |            |
| Any                                      | 454 (25.2) | 325 (18.1) | 647 (39.0) | 229 (13.9) |
| Mild                                     | 348 (19.3) | 242 (13.5) | 422 (25.4) | 165 (10.0) |
| Moderate                                 | 104 (5.8)  | 80 (4.5)   | 216 (13.0) | 60 (3.6)   |
| Severe                                   | 2 (0.1)    | 3 (0.2)    | 9 (0.5)    | 4 (0.2)    |
| Chills <sup>¶</sup>                      |            |            |            |            |
| Any                                      | 113 (6.3)  | 57 (3.2)   | 377 (22.7) | 46 (2.8)   |
| Mild                                     | 87 (4.8)   | 40 (2.2)   | 199 (12.0) | 35 (2.1)   |
| Moderate                                 | 26 (1.4)   | 16 (0.9)   | 161 (9.7)  | 11 (0.7)   |
| Severe                                   | 0 (0.0)    | 1 (0.1)    | 17 (1.0)   | 0 (0.0)    |
| Vomiting <sup>#</sup>                    |            |            |            |            |
| Any                                      | 9 (0.5)    | 9 (0.5)    | 11 (0.7)   | 5 (0.3)    |
| Mild                                     | 8 (0.4)    | 9 (0.5)    | 9 (0.5)    | 5 (0.3)    |
| Moderate                                 | 1 (0.1)    | 0 (0.0)    | 1 (0.1)    | 0 (0.0)    |
| Severe                                   | 0 (0.0)    | 0 (0.0)    | 1 (0.1)    | 0 (0.0)    |
| Diarrhea <sup>p</sup>                    |            |            |            |            |
| Any                                      | 147 (8.2)  | 118 (6.6)  | 137 (8.3)  | 99 (6.0)   |
| Mild                                     | 118 (6.5)  | 100 (5.6)  | 114 (6.9)  | 73 (4.4)   |
| Moderate                                 | 26 (1.4)   | 17 (0.9)   | 21 (1.3)   | 22 (1.3)   |
| Severe                                   | 3 (0.2)    | 1 (0.1)    | 2 (0.1)    | 4 (0.2)    |
| New or worsened muscle pain <sup>¶</sup> |            |            |            |            |
| Any                                      | 251 (13.9) | 149 (8.3)  | 477 (28.7) | 87 (5.3)   |
| Mild                                     | 168 (9.3)  | 100 (5.6)  | 202 (12.2) | 57 (3.5)   |
| Moderate                                 | 82 (4.6)   | 46 (2.6)   | 259 (15.6) | 29 (1.8)   |
| Severe                                   | 1 (0.1)    | 3 (0.2)    | 16 (1.0)   | 1 (0.1)    |
| New or worsened joint pain <sup>¶</sup>  |            |            |            |            |
| Any                                      | 155 (8.6)  | 109 (6.1)  | 313 (18.9) | 61 (3.7)   |
| Mild                                     | 101 (5.6)  | 68 (3.8)   | 161 (9.7)  | 35 (2.1)   |
| Moderate                                 | 52 (2.9)   | 40 (2.2)   | 145 (8.7)  | 25 (1.5)   |
| Severe                                   | 2 (0.1)    | 1 (0.1)    | 7 (0.4)    | 1 (0.1)    |
| Use of antipyretic or pain medication    | 358 (19.9) | 213 (11.9) | 625 (37.7) | 161 (9.8)  |

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

# Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

p Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

From an independent report (*Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med*), in 99 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas)  $97 \pm 8$  months previously who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported in recipients who were followed for 1 month following post Dose 3.

### *Unsolicited Adverse Events*

#### *Serious Adverse Events*

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

#### *Non-Serious Adverse Events*

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-

BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by 4 participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

#### Adolescents 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 adolescents (1,131 Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA); 1,129 placebo) were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents have been followed for at least 2 months after the second dose. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

#### *Solicited Local and Systemic Adverse Reactions*

The mean duration of pain at the injection site after Dose 1 was 2.4 days (range 1 to 10 days), for redness 2.4 days (range 1 to 16 days), and for swelling 1.9 days (range 1 to 5 days) for adolescents in the Pfizer-BioNTech COVID-19 Vaccine group.

**Table 5: Study 2 - Frequency and Percentages of Adolescents With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose - Adolescents 12 Through 15 Years of Age - Safety Population\***

|                            | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Dose 1<br/>N<sup>‡</sup>=1127<br/>n<sup>§</sup> (%)</b> | <b>Placebo<br/>Dose 1<br/>N<sup>‡</sup>=1127<br/>n<sup>§</sup> (%)</b> | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Dose 2<br/>N<sup>‡</sup>=1097<br/>n<sup>§</sup> (%)</b> | <b>Placebo<br/>Dose 2<br/>N<sup>‡</sup>=1078<br/>n<sup>§</sup> (%)</b> |
|----------------------------|---|--|---|--|
| <b>Redness<sup>¶</sup></b> |   |  |   |  |
| Any (>2 cm)                | 65 (5.8)  | 12 (1.1)   | 55 (5.0)  | 10 (0.9)   |

|   |            |            |            |            |
|---|------------|------------|------------|------------|
| Mild                                    | 44 (3.9)   | 11 (1.0)   | 29 (2.6)   | 8 (0.7)    |
| Moderate                                | 20 (1.8)   | 1 (0.1)    | 26 (2.4)   | 2 (0.2)    |
| Severe                                  | 1 (0.1)    | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    |
| Swelling <sup>¶</sup>                   |            |            |            |            |
| Any (>2 cm)                             | 78 (6.9)   | 11 (1.0)   | 54 (4.9)   | 6 (0.6)    |
| Mild                                    | 55 (4.9)   | 9 (0.8)    | 36 (3.3)   | 4 (0.4)    |
| Moderate                                | 23 (2.0)   | 2 (0.2)    | 18 (1.6)   | 2 (0.2)    |
| Severe                                  | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    |
| Pain at the injection site <sup>#</sup> |            |            |            |            |
| Any                                     | 971 (86.2) | 263 (23.3) | 866 (78.9) | 193 (17.9) |
| Mild                                    | 467 (41.4) | 227 (20.1) | 466 (42.5) | 164 (15.2) |
| Moderate                                | 493 (43.7) | 36 (3.2)   | 393 (35.8) | 29 (2.7)   |
| Severe                                  | 11 (1.0)   | 0 (0.0)    | 7 (0.6)    | 0 (0.0)    |

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

# Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

**Table 6: Study 2 - Frequency and Percentages of Adolescents with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose - Adolescents 12 Through 15 Years of Age - Safety Population\***

|                      | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Dose 1<br/>N<sup>‡</sup>=1127<br/>n<sup>§</sup> (%)</b> | <b>Placebo<br/>Dose 1<br/>N<sup>‡</sup>=1127<br/>n<sup>§</sup> (%)</b> | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Dose 2<br/>N<sup>‡</sup>=1097<br/>n<sup>§</sup> (%)</b> | <b>Placebo<br/>Dose 2<br/>N<sup>‡</sup>=1078<br/>n<sup>§</sup> (%)</b> |
|----------------------|---|--|---|--|
| Fever                |   |  |   |  |
| ≥38.0°C              | 114 (10.1)  | 12 (1.1)   | 215 (19.6)  | 7 (0.6)  |
| ≥38.0°C to 38.4°C    | 74 (6.6)  | 8 (0.7)  | 107 (9.8)   | 5 (0.5)  |
| >38.4°C to 38.9°C    | 29 (2.6)  | 2 (0.2)  | 83 (7.6)  | 1 (0.1)  |
| >38.9°C to 40.0°C    | 10 (0.9)  | 2 (0.2)  | 25 (2.3)  | 1 (0.1)  |
| >40.0°C              | 1 (0.1)   | 0 (0.0)  | 0 (0.0)   | 0 (0.0)  |
| Fatigue <sup>¶</sup> |   |  |   |  |
| Any                  | 677 (60.1)  | 457 (40.6)   | 726 (66.2)  | 264 (24.5)   |
| Mild                 | 278 (24.7)  | 250 (22.2)   | 232 (21.1)  | 133 (12.3)   |

|  |            |            |            |            |
|--|------------|------------|------------|------------|
| Moderate   | 384 (34.1) | 199 (17.7) | 468 (42.7) | 127 (11.8) |
| Severe   | 15 (1.3)   | 8 (0.7)    | 26 (2.4)   | 4 (0.4)    |
| Headache <sup>¶</sup>                              |            |            |            |            |
| Any  | 623 (55.3) | 396 (35.1) | 708 (64.5) | 263 (24.4) |
| Mild   | 361 (32.0) | 256 (22.7) | 302 (27.5) | 169 (15.7) |
| Moderate   | 251 (22.3) | 131 (11.6) | 384 (35.0) | 93 (8.6)   |
| Severe   | 11 (1.0)   | 9 (0.8)    | 22 (2.0)   | 1 (0.1)    |
| Chills <sup>¶</sup>                                |            |            |            |            |
| Any  | 311 (27.6) | 109 (9.7)  | 455 (41.5) | 73 (6.8)   |
| Mild   | 195 (17.3) | 82 (7.3)   | 221 (20.1) | 52 (4.8)   |
| Moderate   | 111 (9.8)  | 25 (2.2)   | 214 (19.5) | 21 (1.9)   |
| Severe   | 5 (0.4)    | 2 (0.2)    | 20 (1.8)   | 0 (0.0)    |
| Vomiting <sup>#</sup>                              |            |            |            |            |
| Any  | 31 (2.8)   | 10 (0.9)   | 29 (2.6)   | 12 (1.1)   |
| Mild   | 30 (2.7)   | 8 (0.7)    | 25 (2.3)   | 11 (1.0)   |
| Moderate   | 0 (0.0)    | 2 (0.2)    | 4 (0.4)    | 1 (0.1)    |
| Severe   | 1 (0.1)    | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    |
| Diarrhea <sup>p</sup>                              |            |            |            |            |
| Any  | 90 (8.0)   | 82 (7.3)   | 65 (5.9)   | 43 (4.0)   |
| Mild   | 77 (6.8)   | 72 (6.4)   | 59 (5.4)   | 38 (3.5)   |
| Moderate   | 13 (1.2)   | 10 (0.9)   | 6 (0.5)    | 5 (0.5)    |
| Severe   | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    | 0 (0.0)    |
| New or worsened muscle pain <sup>¶</sup>           |            |            |            |            |
| Any  | 272 (24.1) | 148 (13.1) | 355 (32.4) | 90 (8.3)   |
| Mild   | 125 (11.1) | 88 (7.8)   | 152 (13.9) | 51 (4.7)   |
| Moderate   | 145 (12.9) | 60 (5.3)   | 197 (18.0) | 37 (3.4)   |
| Severe   | 2 (0.2)    | 0 (0.0)    | 6 (0.5)    | 2 (0.2)    |
| New or worsened joint pain <sup>¶</sup>            |            |            |            |            |
| Any  | 109 (9.7)  | 77 (6.8)   | 173 (15.8) | 51 (4.7)   |
| Mild   | 66 (5.9)   | 50 (4.4)   | 91 (8.3)   | 30 (2.8)   |
| Moderate   | 42 (3.7)   | 27 (2.4)   | 78 (7.1)   | 21 (1.9)   |
| Severe   | 1 (0.1)    | 0 (0.0)    | 4 (0.4)    | 0 (0.0)    |
| Use of antipyretic or pain medication <sup>§</sup> | 413 (36.6) | 111 (9.8)  | 557 (50.8) | 95 (8.8)   |

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

# Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

p Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

β Severity was not collected for use of antipyretic or pain medication.

### *Unsolicited Adverse Events*

In the following analyses of Study 2 in adolescents 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

### *Serious Adverse Events*

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

### *Non-Serious Adverse Events*

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

### Booster Dose Following a Primary Series of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY

A subset of Study 2 Phase 2/3 participants of 306 adults 18 through 55 years of age received a booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) approximately 6 months (range of 4.8 to 8.0 months) after completing the primary series. Additionally, a total of 23 Study 2 Phase 1 participants (11 participants 18 through 55 years of age and 12 participants 65 through 85 years of age) received a booster dose of Pfizer-BioNTech COVID-19 Vaccine approximately 8 months (range 7.9 to 8.8 months) after completing the primary series. Safety monitoring after the booster dose was the same as that in the reactogenicity subset who received the primary series.

Among the 306 Phase 2/3 participants, the median age was 42 years (range 19 through 55 years of age), 45.8% were male and 54.2% were female, 81.4% were White, 27.8% were Hispanic/Latino, 9.2% were Black or African American, 5.2% were Asian, and 0.7% were American Indian/Alaska Native. Among the 12 Phase 1 participants 65 through 85 years of age, the median age was 69 years (range 65 through 75 years of age), 6 were male and all were White and Not Hispanic/Latino. Following the booster dose, the median follow-up time was 2.6 months (range 2.1 to 2.9 months) for Phase 1 participants and 2.6 months (range 1.1 to 2.8 months) for Phase 2/3 participants.

### *Solicited Local and Systemic Adverse Reactions*

Table 7 and Table 8 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of a booster dose of Pfizer-BioNTech COVID-19 Vaccine for Phase 2/3 participants 18 through 55 years of age.

In participants who received a booster dose, the mean duration of pain at the injection

site after the booster dose was 2.6 days (range 1 to 8 days), for redness 2.2 days (range 1 to 15 days), and for swelling 2.2 days (range 1 to 8 days).

**Table 7: Study 2 - Frequency and Percentages of Participants With Solicited Local Reactions, By Maximum Severity, Within 7 Days After the Booster Dose of Pfizer-BioNTech COVID-19 Vaccine - Participants 18 through 55 Years of Age\***

| <b>Solicited Local Reaction</b>               | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Booster Dose<br/>N<sup>‡</sup> = 289<br/>n<sup>§</sup> (%)</b> |
|---|--|
| <b>Redness<sup>¶</sup></b>                    |  |
| Any (>2 cm)                                   | 17 (5.9)   |
| Mild  | 10 (3.5)   |
| Moderate                                      | 7 (2.4)  |
| Severe  | 0  |
| <b>Swelling<sup>¶</sup></b>                   |  |
| Any (>2 cm)                                   | 23 (8.0)   |
| Mild  | 13 (4.5)   |
| Moderate                                      | 9 (3.1)  |
| Severe  | 1 (0.3)  |
| <b>Pain at the injection site<sup>#</sup></b> |  |
| Any   | 240 (83.0)   |
| Mild  | 174 (60.2)   |
| Moderate                                      | 65 (22.5)  |
| Severe  | 1 (0.3)  |

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after the booster dose.

Note: No Grade 4 solicited local reactions were reported.

\* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) approximately 6 months after completing the primary series.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: >2.0 to 5.0 cm; Moderate: >5.0 to 10.0 cm; Severe: >10.0 cm.

# Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

**Table 8: Study 2 - Frequency and Percentages of Participants With Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After the Booster Dose of Pfizer-BioNTech COVID-19 Vaccine - Participants 18 through 55 Years of Age\***

| <b>Solicited Systemic Reaction</b> | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>Booster Dose</b> |
|------------------------------------|--|
|------------------------------------|--|

|  | <b>N‡ = 289</b><br><b>n§ (%)</b> |
|--|----------------------------------|
| <b>Fever</b>                                       |                                  |
| ≥38.0°C  | 25 (8.7)                         |
| ≥38.0°C to 38.4°C                                  | 12 (4.2)                         |
| >38.4°C to 38.9°C                                  | 12 (4.2)                         |
| >38.9°C to 40.0°C                                  | 1 (0.3)                          |
| >40.0°C  | 0                                |
| <b>Fatigue¶</b>                                    |                                  |
| Any  | 184 (63.7)                       |
| Mild   | 68 (23.5)                        |
| Moderate   | 103 (35.6)                       |
| Severe   | 13 (4.5)                         |
| <b>Headache¶</b>                                   |                                  |
| Any  | 140 (48.4)                       |
| Mild   | 83 (28.7)                        |
| Moderate   | 54 (18.7)                        |
| Severe   | 3 (1.0)                          |
| <b>Chills¶</b>                                     |                                  |
| Any  | 84 (29.1)                        |
| Mild   | 37 (12.8)                        |
| Moderate   | 44 (15.2)                        |
| Severe   | 3 (1.0)                          |
| <b>Vomiting#</b>                                   |                                  |
| Any  | 5 (1.7)                          |
| Mild   | 5 (1.7)                          |
| Moderate   | 0                                |
| Severe   | 0                                |
| <b>Diarrhea<sup>p</sup></b>                        |                                  |
| Any  | 25 (8.7)                         |
| Mild   | 21 (7.3)                         |
| Moderate   | 4 (1.4)                          |
| Severe   | 0                                |
| <b>New or worsened muscle pain¶</b>                |                                  |
| Any  | 113 (39.1)                       |
| Mild   | 52 (18.0)                        |
| Moderate   | 57 (19.7)                        |
| Severe   | 4 (1.4)                          |
| <b>New or worsened joint pain¶</b>                 |                                  |
| Any  | 73 (25.3)                        |
| Mild   | 36 (12.5)                        |
| Moderate   | 36 (12.5)                        |
| Severe   | 1 (0.3)                          |
| Use of antipyretic or pain medication <sup>β</sup> | 135 (46.7)                       |

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after the booster dose.



Note: No Grade 4 solicited systemic reactions were reported.

\* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) approximately 6 months after completing the primary series.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

§ n = Number of participants with the specified reaction.

¶ Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

# Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

Ⓟ Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

Ⓡ Severity was not collected for use of antipyretic or pain medication.

In Phase 1 participants  $\geq 65$  years of age ( $n = 12$ ), local reaction pain at the injection site ( $n = 8$ , 66.7%) and systemic reactions fatigue ( $n = 5$ , 41.7%), headache ( $n = 5$ , 41.7%), chills ( $n = 2$ , 16.7%), muscle pain ( $n = 4$ , 33.3%), and joint pain ( $n = 2$ , 16.7%) were reported after the booster dose. No participant in this age group reported a severe systemic event or fever after the booster dose.

### *Unsolicited Adverse Events*

Overall, the 306 participants who received a booster dose, had a median follow-up time of 2.6 months after the booster dose to the cut-off date (June 17, 2021).

In an analysis of all unsolicited adverse events reported following the booster dose, through 1 month after the booster dose, in participants 18 through 55 years of age ( $N = 306$ ), those assessed as adverse reactions not already captured by solicited local and systemic reactions were lymphadenopathy ( $n = 16$ , 5.2%), nausea ( $n = 2$ , 0.7%), decreased appetite ( $n = 1$ , 0.3%), rash ( $n = 1$ , 0.3%), and pain in extremity ( $n = 1$ , 0.3%).

### *Serious Adverse Events*

Of the 306 participants who received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 30 days after the booster dose. One participant reported a serious adverse event 61 days after the booster dose that was assessed as unrelated to vaccination.

### Booster Dose Following Primary Vaccination with Another Authorized COVID-19 Vaccine

The safety of a Pfizer-BioNTech COVID-19 Vaccine booster dose (30 mcg modRNA) in individuals who completed primary vaccination with another authorized COVID-19 Vaccine (heterologous booster dose) is inferred from the safety of a Pfizer-BioNTech COVID-19 Vaccine booster dose administered following completion of Pfizer-BioNTech COVID-19 Vaccine primary series (homologous booster dose) and from data from an independent National Institutes of Health (NIH) study Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series ( $N=151$ ), a Janssen COVID-19 Vaccine single dose ( $N=156$ ), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series ( $N=151$ ) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three

vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA). Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported in the study following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following a Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose.

## **6.2 Post Authorization Experience**

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis

Gastrointestinal Disorders: diarrhea, vomiting

Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)

Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

Nervous System Disorders: syncope

## **8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS<sup>5</sup>**

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events\* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

\*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent 1 of the outcomes listed above

### Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should

complete and submit a VAERS form to FDA using 1 of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to [info@vaers.org](mailto:info@vaers.org).

**IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:**

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within 1 month prior.
2. In Box 18, description of the event:
  - a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
  - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
  - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
  - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
  - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

### Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

| Website | Fax number | Telephone number |
|---------|------------|------------------|
|---------|------------|------------------|

5 Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

## **10 DRUG INTERACTIONS**

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## **11 USE IN SPECIFIC POPULATIONS**

### **11.1 Pregnancy**

#### Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (modRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on 4 occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

### **11.2 Lactation**

#### Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

### **11.3 Pediatric Use**

Emergency Use Authorization of this formulation of Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with gray caps and labels with gray borders, in adolescents 12 through 17 years of age is based on safety and effectiveness data in this age group and in adults.

For individuals 5 through 11 years of age, a different presentation of this formulation of the Pfizer-BioNTech COVID-19 Vaccine is authorized.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 5 years of age.

### **11.4 Geriatric Use**

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older who received the primary series and their data contributes to the overall assessment of safety and efficacy [see *Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)*]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine in individuals 65 years of age and older is based on safety data in 12 booster dose recipients 65 through 85 years of age and 306 booster dose recipients 18 through 55 years of age in Study 2. The effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine in individuals 65 years of age and older is based on effectiveness data in 306 booster dose recipients 18 through 55 years of age in Study 2.

### **11.5 Use in Immunocompromised**

From an independent report (*Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med*), safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine have been evaluated in persons that received solid organ transplants. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

## **13 DESCRIPTION**

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials with gray caps and labels with gray borders. Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with gray caps and labels with gray borders contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with gray caps and labels with gray borders also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

## **14 CLINICAL PHARMACOLOGY**

### **14.1 Mechanism of Action**

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against

## 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

### 18.1 Efficacy of Primary Series in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 9 presents the specific demographic characteristics in the studied population.

**Table 9: Demographics (population for the primary efficacy endpoint)\***

|   | <b>Pfizer-BioNTech COVID-19 Vaccine<sup>†</sup><br/>(N=18,242)<br/>n (%)</b> | <b>Placebo<br/>(N=18,379)<br/>n (%)</b> |
|---|--|---|
| <b>Sex</b>                              |  |   |
| Male                                    | 9318 (51.1)  | 9225 (50.2)                             |
| Female                                  | 8924 (48.9)  | 9154 (49.8)                             |
| <b>Age (years)</b>                      |  |   |
| Mean (SD)                               | 50.6 (15.70)   | 50.4 (15.81)                            |
| Median                                  | 52.0   | 52.0                                    |
| Min, max                                | (12, 89)   | (12, 91)                                |
| <b>Age group</b>                        |  |   |
| $\geq 12$ through 15 years <sup>‡</sup> | 46 (0.3)   | 42 (0.2)                                |
| $\geq 16$ through 17 years              | 66 (0.4)   | 68 (0.4)                                |
| $\geq 16$ through 64                    | 14 216 (77.0)  | 14 209 (77.0)                           |

|   |               |               |
|---|---------------|---------------|
| years                                     | 14,210 (77.5) | 14,299 (77.6) |
| ≥65 through 74 years                      | 3176 (17.4)   | 3226 (17.6)   |
| ≥75 years                                 | 804 (4.4)     | 812 (4.4)     |
| Race                                      |               |               |
| White                                     | 15,110 (82.8) | 15,301 (83.3) |
| Black or African American                 | 1617 (8.9)    | 1617 (8.8)    |
| American Indian or Alaska Native          | 118 (0.6)     | 106 (0.6)     |
| Asian                                     | 815 (4.5)     | 810 (4.4)     |
| Native Hawaiian or other Pacific Islander | 48 (0.3)      | 29 (0.2)      |
| Other <sup>§</sup>                        | 534 (2.9)     | 516 (2.8)     |
| Ethnicity                                 |               |               |
| Hispanic or Latino                        | 4886 (26.8)   | 4857 (26.4)   |
| Not Hispanic or Latino                    | 13,253 (72.7) | 13,412 (73.0) |
| Not reported                              | 103 (0.6)     | 110 (0.6)     |
| Comorbidities <sup>¶</sup>                |               |               |
| Yes                                       | 8432 (46.2)   | 8450 (46.0)   |
| No  | 9810 (53.8)   | 9929 (54.0)   |

\* All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least 1 dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.

§ Includes multiracial and not reported.

¶ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease

- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 10.

**Table 10: Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup - Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy (7 Days) Population**

| <b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*</b>        |   |   |  |
|--|---|---|--|
| <b>Subgroup</b>  | <b>Pfizer-BioNTech COVID-19 Vaccine†<br/>N‡=18,198<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Placebo<br/>N‡=18,325<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Vaccine Efficacy<br/>%<br/>(95% CI)</b> |
| All subjects <sup>p</sup>  | 8<br>2.214 (17,411)   | 162<br>2.222 (17,511)   | 95.0<br>(90.3, 97.6) <sup>β</sup>          |
| 16 through 64 years  | 7<br>1.706 (13,549)   | 143<br>1.710 (13,618)   | 95.1<br>(89.6, 98.1) <sup>à</sup>          |
| 65 years and older   | 1<br>0.508 (3848)   | 19<br>0.511 (3880)  | 94.7<br>(66.7, 99.9) <sup>à</sup>          |
| <b>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection</b> |   |   |  |
| <b>Subgroup</b>  | <b>Pfizer-BioNTech COVID-19 Vaccine†<br/>N‡=19,965<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Placebo<br/>N‡=20,172<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Vaccine Efficacy<br/>%<br/>(95% CI)</b> |
| All subjects <sup>p</sup>  | 9<br>2.332 (18,559)   | 169<br>2.345 (18,708)   | 94.6<br>(89.9, 97.3) <sup>β</sup>          |
| 16 through 64 years  | 8<br>1.802 (14,501)   | 150<br>1.814 (14,627)   | 94.6<br>(89.1, 97.7) <sup>à</sup>          |
| 65 years and older   | 1<br>0.530 (4044)   | 19<br>0.532 (4067)  | 94.7<br>(66.8, 99.9) <sup>à</sup>          |

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants in the specified group.



- § n1 = Number of participants meeting the endpoint definition.  
 ¶ Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.  
 # n2 = Number of participants at risk for the endpoint.  
 p No confirmed cases were identified in adolescents 12 through 15 years of age.  
 β Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for  $\theta = r(1-VE)/(1+r(1-VE))$ , where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.  
 à Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

## 18.2 Efficacy of Primary Series in Adolescents 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in adolescents 12 through 15 years of age is presented in Table 11.

**Table 11: Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 - Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population**

| <b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*</b>        |   |   |  |
|--|---|---|--|
|  | <b>Pfizer-BioNTech<br/>COVID-19<br/>Vaccine†<br/>N‡=1005<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Placebo<br/>N‡=978<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b>  | <b>Vaccine Efficacy<br/>%<br/>(95% CI<sup>p</sup>)</b> |
| Adolescents 12 through 15 years of age   | 0<br>0.154 (1001)   | 16<br>0.147 (972)   | 100.0<br>(75.3, 100.0)                                 |
| <b>First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection</b> |   |   |  |
|  | <b>Pfizer-BioNTech<br/>COVID-19<br/>Vaccine†<br/>N‡=1119<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Placebo<br/>N‡=1110<br/>Cases<br/>n1§<br/>Surveillance<br/>Time¶ (n2#)</b> | <b>Vaccine Efficacy<br/>%<br/>(95% CI<sup>p</sup>)</b> |

|  |                   |                    |                        |
|--|-------------------|--------------------|------------------------|
| Adolescents 12 through 15 years of age | 0<br>0.170 (1109) | 18<br>0.163 (1094) | 100.0<br>(78.1, 100.0) |
|--|-------------------|--------------------|------------------------|

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

† Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

‡ N = Number of participants in the specified group.

§ n1 = Number of participants meeting the endpoint definition.

¶ Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

# n2 = Number of participants at risk for the endpoint.

▷ Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

### 18.3 Immunogenicity of Primary Series in Adolescents 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers (NT50) 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing adolescents 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 12).

**Table 12: Summary of Geometric Mean Ratio for 50% Neutralizing Titer - Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) -Participants Without Evidence of Infection up to 1 Month After Dose 2 - Dose 2 Evaluable Immunogenicity Population**

|   |                               | <b>Pfizer-BioNTech COVID-19 Vaccine*</b>         |  |   |   |
|---|-------------------------------|--|--|---|---|
|   |                               | <b>12 Through 15 Years<br/>n<sup>†</sup>=190</b> | <b>16 Through 25 Years<br/>n<sup>†</sup>=170</b> | <b>12 Through 15 Years/<br/>16 Through 25 Years</b> |   |
| <b>Assay</b>  | <b>Time Point<sup>‡</sup></b> | <b>GMT<sup>§</sup><br/>(95% CI<sup>§</sup>)</b>  | <b>GMT<sup>§</sup><br/>(95% CI<sup>§</sup>)</b>  | <b>GMR<sup>¶</sup><br/>(95% CI<sup>¶</sup>)</b>     | <b>Met Noninferiority Objective<sup>#</sup><br/>(Y/N)</b> |
| SARS-CoV-2 neutralization assay - NT50 (titer) <sup>▷</sup> | 1 month after Dose 2          | 1239.5<br>(1095.5, 1402.5)                       | 705.1<br>(621.4, 800.2)                          | 1.76<br>(1.47, 2.10)                                | Y   |

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT

= geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

\* Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

† n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.

‡ Protocol-specified timing for blood sample collection.

§ GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$ .

¶ GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12 through 15 years of age] – Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).

# Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.

▷ SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA\_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

#### **18.4 Immunogenicity of a Booster Dose Following a Pfizer-BioNTech COVID-19 Vaccine Primary Series in Participants 18 Through 55 Years of Age**

Effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA) was based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA\_WA1/2020). In Study 2, analyses of NT50 1 month after the booster dose compared to 1 month after the primary series in individuals 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster vaccination demonstrated noninferiority for both geometric mean ratio (GMR) and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a  $\geq 4$ -fold rise in NT50 from baseline (before primary series). These analyses are summarized in Table 13 and Table 14.

**Table 13: Geometric Mean 50% Neutralizing Titer (SARS-CoV-2 USA\_WA1/2020) - Comparison of 1 Month After Booster Dose to 1 Month After Primary Series - Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose\* - Booster Dose Evaluable Immunogenicity Population†**

|  |  | <b>1 Month After</b> | <b>1 Month After Primary</b> | <b>1 Month After Booster Dose/ 1 Month</b> | <b>Met Noninferiority</b> |
|--|--|----------------------|------------------------------|--|---------------------------|
|--|--|----------------------|------------------------------|--|---------------------------|

| Assay   | n <sup>‡</sup> | Booster Dose GMT <sup>§</sup><br>(95% CI <sup>§</sup> ) | Primary Series GMT <sup>§</sup><br>(95% CI <sup>§</sup> ) | After Primary Series GMR <sup>¶</sup><br>(97.5% CI <sup>¶</sup> ) | Noninferiority Objective <sup>#</sup><br>(Y/N) |
|---|----------------|---|---|---|--|
| SARS-CoV-2 neutralization assay - NT50 (titer) <sup>Ⓟ</sup> | 212            | 2466.0<br>(2202.6, 2760.8)                              | 750.6<br>(656.2, 858.6)                                   | 3.29<br>(2.77, 3.90)  | Y  |

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

\* Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of Pfizer-BioNTech COVID-19 Vaccine) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after the booster dose were included in the analysis.

† All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

‡ n = Number of participants with valid and determinate assay results at both sampling time points within specified window.

§ GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$ .

¶ GMRs and 2-sided 97.5% CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution).

# Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the GMR is  $>0.67$  and the point estimate of the GMR is  $\geq 0.80$ .

Ⓟ SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA\_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

**Table 14: Seroreponse Rate for 50% Neutralizing Titer (SARS-CoV-2 USA\_WA1/2020) - Comparison of 1 Month After Booster Dose to 1 Month After Primary Series - Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose\* - Booster Dose Evaluable Immunogenicity Population†**

|  |  | 1 Month | 1 Month | Difference<br>(1 Month<br>After<br>Booster |  |
|--|--|---------|---------|--|--|
|--|--|---------|---------|--|--|

| <b>Assay</b>  | <b>N<sup>‡</sup></b> | <b>After<br/>Booster<br/>Dose<br/>n<sup>§</sup><br/>% (95%<br/>CI<sup>¶</sup>)</b> | <b>After<br/>Primary<br/>Series<br/>n<sup>§</sup><br/>% (95%<br/>CI<sup>¶</sup>)</b> | <b>Booster<br/>Dose - 1<br/>Month<br/>After<br/>Primary<br/>Series)<br/>%<sup>#</sup><br/>(97.5%<br/>CI<sup>Ⓟ</sup>)</b> | <b>Met<br/>Noninferiority<br/>Objective<sup>β</sup><br/>(Y/N)</b> |
|---|----------------------|--|--|--|---|
| SARS-CoV-2 neutralization assay - NT50 (titer) <sup>à</sup> | 200                  | 199<br>99.5 (97.2, 100.0)  | 196<br>98.0 (95.0, 99.5)   | 1.5 (-0.7, 3.7)  | Y   |

Abbreviations: CI = confidence interval; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Seroresponse is defined as achieving a  $\geq 4$ -fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result  $\geq 4 \times$  LLOQ is considered a seroresponse.

Note: Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA).

- \* Participants who had no serological or virological evidence (up to 1 month after receipt of booster vaccination) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.
- † All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.
- ‡ N = number of participants with valid and determinate assay results for the specified assay at baseline, 1 month after Dose 2 and 1 month after the booster dose within specified window. These values are the denominators for the percentage calculations.
- § n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
- ¶ Exact 2-sided CI based on the Clopper and Pearson method.
- # Difference in proportions, expressed as a percentage (1 month after booster dose - 1 month after Dose 2).
- Ⓟ Adjusted Wald 2-sided CI for the difference in proportions, expressed as a percentage.
- β Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the percentage difference is  $> -10\%$ .
- à SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA\_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

## 18.5 Immunogenicity in Solid Organ Transplant Recipients

From an independent report (Kamar N, Abravanel F, Marion O, et al. Three doses of an

*mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med*), a single arm study has been conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously. A third dose of the Pfizer-BioNTech COVID-19 vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% (67 of 99 patients) 4 weeks after the third dose.

### **18.6 Immunogenicity of a Booster Dose Following Primary Vaccination with Another Authorized COVID-19 Vaccine**

Effectiveness of a Pfizer-BioNTech COVID-19 Vaccine booster dose (30 mcg modRNA) in individuals who completed primary vaccination with another authorized COVID-19 Vaccine (heterologous booster dose) is inferred from immunogenicity data supporting effectiveness of a Pfizer-BioNTech COVID-19 Vaccine booster dose administered following completion of Pfizer-BioNTech COVID-19 Vaccine primary series and from immunogenicity data from an independent NIH study Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine (30 mcg modRNA). Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Pfizer-BioNTech COVID-19 Vaccine was demonstrated regardless of primary vaccination.

## **19 HOW SUPPLIED/STORAGE AND HANDLING**

The information in this section applies to the Pfizer-BioNTech COVID-19 Vaccine that is supplied in multiple dose vials with gray caps and labels with gray borders. These multiple dose vials are supplied in a carton containing 10 multiple dose vials (NDC 59267-1025-4) or 25 multiple dose vials (NDC 59267-1025-3). One vial contains 6 doses of 0.3 mL.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

### **Vial Storage Prior to Use**

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F).

Once received, frozen vials may be immediately transferred to the refrigerator [2°C to

8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 6 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.

Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may also arrive at 2°C to 8°C. If received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

Regardless of storage condition, vaccine should not be used after 6 months from the date of manufacture printed on the vial and cartons.

### Vial Storage During Use

If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after first puncture.

### **DO NOT DILUTE PRIOR TO USE.**

Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Full EUA Prescribing Information supersedes the number of hours printed on vial labels and cartons.

### Transportation of Vials

If local redistribution is needed, vials may be transported at -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F).

## **20 PATIENT COUNSELING INFORMATION**

Advise the recipient or caregiver to read the Vaccine Information Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## **21 CONTACT INFORMATION**

For general questions, visit the website or call the telephone number provided below.

| Website  | Telephone number |
|--|------------------|
| <a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> |                  |



1-877-829-2619  
(1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).



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**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS  
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH  
COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)  
FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND OLDER**

**FOR 12 YEARS OF AGE AND OLDER**

**You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.**

**This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.**

**The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.<sup>6</sup>**

**COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:**



- a 2-dose primary series to individuals 12 through 15 years of age;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise;
- a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

**The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:**

- a 2-dose primary series to individuals 12 years of age and older;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise;
- a single booster dose to individuals 18 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

## **WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

### **WHAT IS COVID-19?**

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### **WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?**

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine when prepared according to their respective instructions for use, can be used interchangeably.

For more information on EUA, see the "**What is an Emergency Use Authorization**

**(EUA)?**" section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?**

**Tell the vaccination provider about all of your medical conditions, including if you:**

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

## **HOW IS THE VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

**Primary Series:** The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

**Booster Dose:**

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals 18 years of age and older.
- A single booster dose of the vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding timing of the booster dose.

The vaccine may not protect everyone.

## **WHO SHOULD NOT GET THE VACCINE?**

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE VACCINES?**

COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:

- mRNA and lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains the following additional ingredients: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

### **HAS THE VACCINE BEEN USED BEFORE?**

Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is authorized for use in individuals 12 years of age and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

### **WHAT ARE THE BENEFITS OF THE VACCINE?**

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

### **WHAT ARE THE RISKS OF THE VACCINE?**

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

| <b>Website</b>   | <b>Fax number</b> | <b>Telephone number</b> |
|--|-------------------|-------------------------|
| <a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a> | 1-866-635-8337    | 1-800-438-1985          |

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19

vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

### **WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?**

Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

### **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?**

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

### **CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?**

Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

### **WHAT IF I AM IMMUNOCOMPROMISED?**

If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

### **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### **WILL THE VACCINE GIVE ME COVID-19?**

No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

### **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

### **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

| <b>Global website</b>                                      | <b>Telephone number</b> |
|--|-------------------------|
| <a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> |                         |



1-877-829-2619  
(1-877-VAX-CO19)

### **HOW CAN I LEARN MORE?**

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

### **WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit:

<https://www.cdc.gov/vaccines/programs/iis/about.html>

### **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

### **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

### **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

### **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use

of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



Manufactured by  
Pfizer Inc., New York, NY 10017

Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1451-13.0

Revised: 19 November 2021

Scan to capture that this Fact Sheet  
was provided to vaccine recipient for  
the electronic medical  
records/immunization information  
systems.  
GDTI: 0886983000332

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6 When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

## **PRINCIPAL DISPLAY PANEL - 2.25 mL Vial Label**

Pfizer-BioNTech COVID-19 Vaccine  
DO NOT DILUTE  
Age 12y & older

Vial contains 6 doses of 0.3 mL

For intramuscular use. Contains no preservative.  
For use under Emergency Use Authorization.

After first use store at 2 to 25°C (35 to 77°F) and discard after 6 hours.

First use date and time:

PAA177758

LOT/MFG

NDC 59267-1025-1



## PRINCIPAL DISPLAY PANEL - 25 Vial Carton

NDC 59267-1025-3

Pfizer-BioNTech

COVID-19 Vaccine

Suspension for Intramuscular Injection

DO NOT DILUTE

25 Multiple Dose Vials

Each vial contains 6 doses of 0.3 mL

For 12 years of age and older

BIONTECH

Pfizer

Rx only



**Pfizer-BioNTech**  
**COVID-19 Vaccine**  
*Suspension for Intramuscular Injection*

NDC 59267-1025-3

**DO NOT DILUTE**  
**25 Multiple Dose Vials**

Each vial contains 6 doses of 0.3 mL  
For 12 years of age and older

BIONTECH 



Rx only

For storage and expiry information, see  
FDA-authorized Fact Sheet or scan QR code.  
Store in this carton to protect from light.

After first use, store the vaccine at  
2°C to 25°C (35°F to 77°F).

Discard 6 hours after first use.

Contains no preservative.

For use under Emergency Use Authorization.



FPO: QR Code  
<https://www.pfizer.com/pfizer/covidavax>



IMPRINT AREA  
"READS THIS WAY"

LOT/MFG:

Rx only

BIONTECH 

**Pfizer-BioNTech**  
**COVID-19 Vaccine**  
*Suspension for Intramuscular Injection*  
**DO NOT DILUTE**  
**25 Multiple Dose Vials**  
Each vial contains 6 doses of 0.3 mL  
For 12 years of age and older

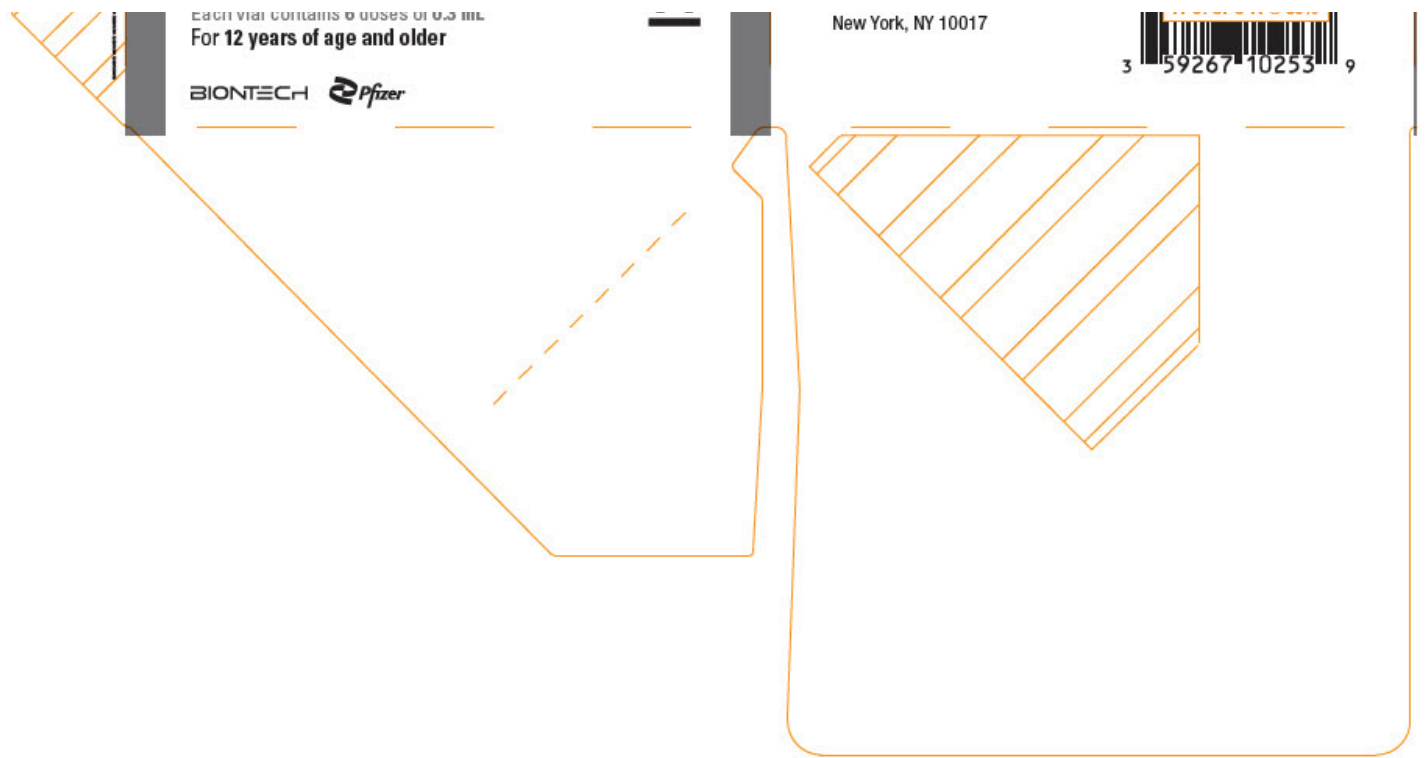


**Pfizer-BioNTech**  
**COVID-19 Vaccine**  
*Suspension for Intramuscular Injection*  
**DO NOT DILUTE**  
**25 Multiple Dose Vials**  
Each vial contains 6 doses of 0.3 mL

PAA177821

Manufactured for  
BioNTech  
Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Manufactured by  
Pfizer Inc.





## PRINCIPAL DISPLAY PANEL - 10 Vial Carton

NDC 59267-1025-4

Pfizer-BioNTech  
COVID-19 Vaccine  
Suspension for Intramuscular Injection

DO NOT DILUTE

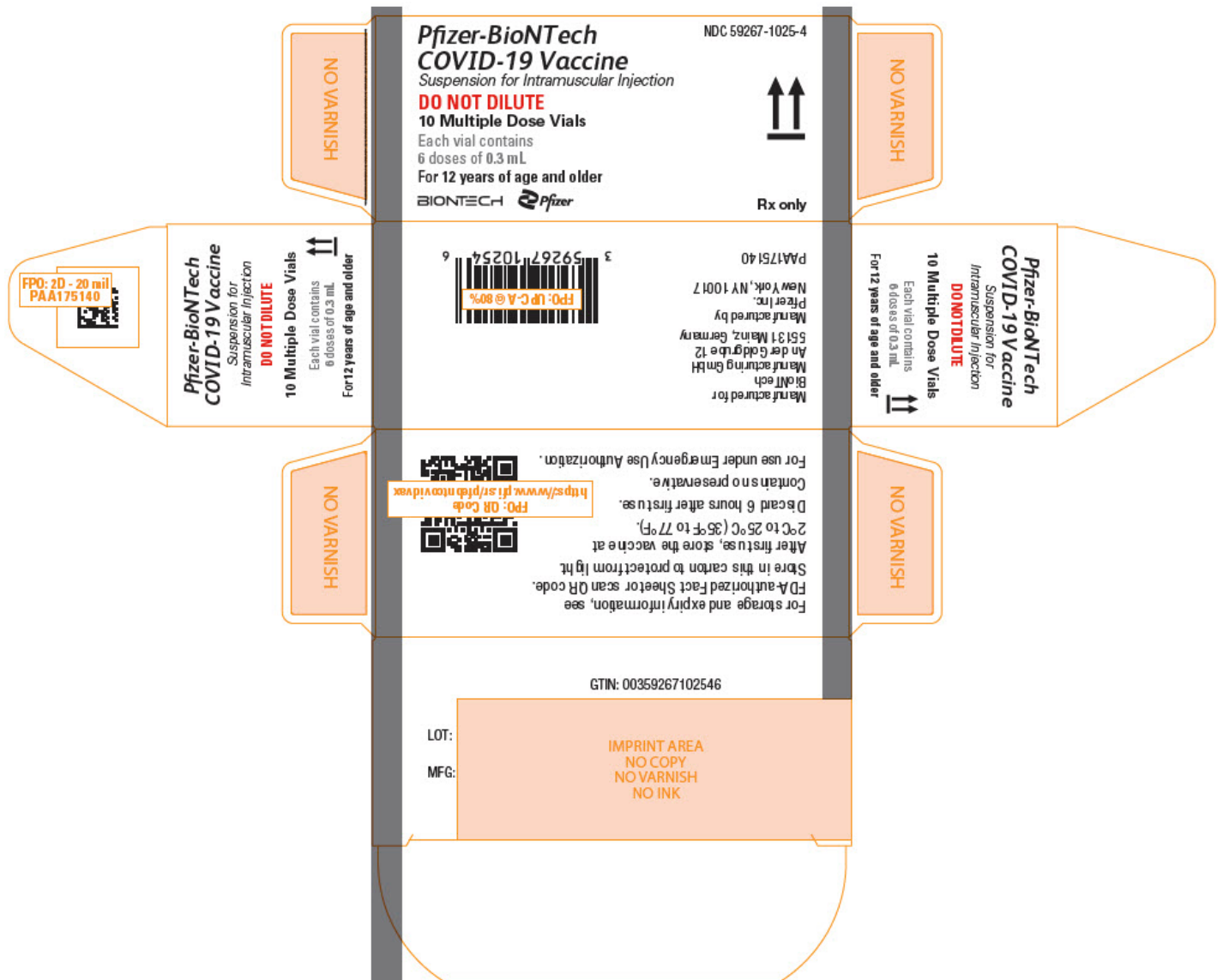
10 Multiple Dose Vials

Each vial contains  
6 doses of 0.3 mL

For 12 years of age and older

BIONTECH  
Pfizer

Rx only



## PFIZER-BIONTECH COVID-19 VACCINE

bnt162b2 injection, suspension

### Product Information

|                         |               |                    |                |
|-------------------------|---------------|--------------------|----------------|
| Product Type            | VACCINE       | Item Code (Source) | NDC:59267-1025 |
| Route of Administration | INTRAMUSCULAR |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength            |
|--|-------------------|---------------------|
| TOZINAMERAN (UNII: 5085ZFP6SJ) (TOZINAMERAN - UNII:5085ZFP6SJ) | TOZINAMERAN       | 0.225 mg in 2.25 mL |

### Inactive Ingredients

| Ingredient Name             | Strength           |
|-----------------------------|--------------------|
| ALC-0159 (UNII: PJH39UMU6H) | 0.41 mg in 2.25 mL |

|  |                     |
|--|---------------------|
| <b>ALC-0315</b> (UNII: AVX8DX713V)                                   | 3.22 mg in 2.25 mL  |
| <b>TROMETHAMINE</b> (UNII: 023C2WHX2V)                               | 0.45 mg in 2.25 mL  |
| <b>TROMETHAMINE HYDROCHLORIDE</b> (UNII: 383V75M34E)                 | 2.97 mg in 2.25 mL  |
| <b>SUCROSE</b> (UNII: C151H8M554)                                    | 231.8 mg in 2.25 mL |
| <b>1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE</b> (UNII: 043IP12M0K) | 0.7 mg in 2.25 mL   |
| <b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)                                | 1.4 mg in 2.25 mL   |
| <b>WATER</b> (UNII: 059QF0KO0R)                                      |                     |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59267-1025-3 | 25 in 1 CARTON  |                      |                    |
| 1 | NDC:59267-1025-1 | 2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:59267-1025-4 | 10 in 1 CARTON  |                      |                    |
| 2 | NDC:59267-1025-1 | 2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category          | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------------|--|----------------------|--------------------|
| EMERGENCY USE AUTHORIZATION |  | 10/30/2021           |                    |

**Labeler** - Pfizer Manufacturing Belgium NV (370156507)

**Registrant** - Pfizer Inc (113480771)

### Establishment

| Name                            | Address | ID/FEI    | Business Operations   |
|---------------------------------|---------|-----------|---|
| Pfizer Manufacturing Belgium NV |         | 370156507 | ANALYSIS(59267-1025) , MANUFACTURE(59267-1025) , PACK(59267-1025) , LABEL(59267-1025) |

### Establishment

| Name  | Address | ID/FEI    | Business Operations                                |
|---|---------|-----------|--|
| Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC |         | 174350868 | ANALYSIS(59267-1025) , API MANUFACTURE(59267-1025) |

### Establishment

| Name       | Address | ID/FEI    | Business Operations  |
|------------|---------|-----------|----------------------|
| Pfizer Inc |         | 004954111 | ANALYSIS(59267-1025) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

|                                |  |           |                      |
|--------------------------------|--|-----------|----------------------|
| Pfizer Ireland Pharmaceuticals |  | 985586408 | ANALYSIS(59267-1025) |
|--------------------------------|--|-----------|----------------------|

## Establishment

| Name  | Address | ID/FEI    | Business Operations  |
|---|---------|-----------|----------------------|
| BioNTech Innovative Manufacturing Services GmbH |         | 537365801 | ANALYSIS(59267-1025) |

## Establishment

| Name                        | Address | ID/FEI    | Business Operations                                |
|-----------------------------|---------|-----------|--|
| BioNTech Manufacturing GmbH |         | 314382536 | ANALYSIS(59267-1025) , API MANUFACTURE(59267-1025) |

## Establishment

| Name                                | Address | ID/FEI    | Business Operations                                |
|-------------------------------------|---------|-----------|--|
| BioNTech Manufacturing Marburg GmbH |         | 313270335 | ANALYSIS(59267-1025) , API MANUFACTURE(59267-1025) |

Revised: 11/2021

Pfizer Manufacturing Belgium NV